K111329

SEP - 6 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Feb. 20, 2011

1. Company and Correspondent making the submission:

Name – NUGA MEDICAL Co., Ltd.

Address – Donghwa Medical Instrument Complex, #1642-10, Donghwa 3-Ri, Munmak-Eup, Wonju-Si, Gangwon-Do, Korea

Telephone – +82-33-730-0001

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Contact – Ms. Ji Hye, Lee

Internet – http://www.nuga.kr

2. Device :

Proprietary name	: NM-7000
Common Name	: Personal Heating Therapeutic Device
Classification Name	: Multifunction physical therapy table, Infrared lamp, Therapeutic massager

3. Predicate Device :

Manufacturer	: MIGUN MEDICAL INSTRUMENT Co., Ltd.
Device	: HY-7000
510(k) Number	: K041200 (Decision Date - Jun. 17. 2004)

4. Classifications Names & Citations :

21CFR890.5880, 21CFR890.5500, 21CFR890.5660, JFB, ILY, ISA Multifunction physical therapy table, Infrared lamp, Therapeutic massager, Class2

5. Description :

The NM-7000 Personal Heating Therapeutic Device is an electric multifunctional physical energy device. Its use is to provide muscle relaxing therapy to patients via a thermal function and massage. It includes ceramics which emit far infrared radiation and is for temporary easing of muscle pains, joint aches, and stiffening.

This device is made up of the main mat, auxiliary mat, frame, 5ball, 9ball external light projector, Leg holding heater as well as a regulator that can regulate and control the function of the device. Inside the main mat, 7 internal heating roller type ceramics, which can massage from the cervical vertebra to the lumbar, have been installed. A motor that can operate the heating ceramics top down, the main pcb, and a temperature sensor that can control the temperature are attached to the internal heating ceramics.

When massaging the cervical vertebra to lumbar, place the upper body over the main mat, and place the leg on the auxiliary mat which has the heating function. Also, when massaging the leg, it can be used the other way. The internal light projector moves and massages the area where the muscle has cramped and is aching and at the same time, provides thermotherapy that can relax the muscle.

The 5ball or 9ball Tourmanium projector was designed in a way it can manually provide thermotherapy and stimulation for the aching area and can easily be selected according to the aching area.
The leg holding heater can additionally provide thermotherapy for the knee or calf and was designed in a way it can be attached and fixed after wrapping the frame with a integrated Velcro band.

The main mat and auxiliary mat are both separate module types and are installed above the frame. They should be connected with the Velcro of each mat area, attached, and fixed.
The connection cable that can link the main mat with the auxiliary mat provides power for the heater from the main mat to the auxiliary mat.
The electronic components of each module such as the traction motor are loaded above the lower plywood of each module.

6. Indications for use :

The intended use of the NM-7000 is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the infrared lamps provide topical heating for;

- Temporary relief of minor muscle and joint pain, and stiffness
- The temporary relief of minor joint pain associated with arthritis
- The temporary increase in local circulation where applied
- Relaxation of muscles

7. Comparison with predicate device :

NUGA MEDICAL Co., Ltd., believes that the Personal Heating Therapeutic Device (NM-7000) is substantially equivalent to the HY-7000 of MIGUN MEDICAL INSTRUMENT Co., Ltd..

The similarities are Intended Use, Electrical Power, Heating unit, Temperature, Operating modes and Preprogrammed setting. And Dimension and Weight and Max temperature (10 degrees higher) is different, but it is not influenced by function and safety.

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-2-38 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). Temperature testing was conducted. All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification NUGA MEDICAL Co., Ltd. concludes that The NM-7000 is safe and effective with respect to and substantially equivalent to predicate devices as described herein.

10. NUGA MEDICAL Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP - 6 2011

Nuga Medical Co., Ltd.
% Underwriters Laboratories, Inc.
Mr. Marc N. Mouser
2600 NW Lake Road
Camas, Washington 98607

Re: K111329
Trade/Device Name: Personal Heating Therapeutic Device / NM-7000
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table
Regulatory Class: Class II
Product Code: JFB, ILY, ISA
Dated: August 18, 2011
Received: August 21, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number(if known):

Device Name: Personal Heating therapeutic device / NM-7000

Indications for Use:

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- The temporary relief of minor joint pain associated with arthritis
- The temporary increase in local circulation where applied
- Relaxation of muscles

Prescription Use_____ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111329